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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHIRE CANADA INC., et al., Plaintiffs, v. MYLAN INC., et al., Defendants.	Civil Action. No.: 09-CIV-2555 (PGG)(KNF) **DEFENDANTS' ANSWER TO THE AMENDED COMPLAINT**

Defendants Mylan Inc., Mylan Pharmaceuticals Inc. and Matrix Laboratories Limited (collectively "Defendants" or "Mylan"), by their undersigned counsel, for their Answer to the Amended Complaint of Shire Canada Inc., Shire International Licensing B.V., and Shire US Inc. (collectively "Shire" or "Plaintiffs"), state as follows:

The Parties

1. On information and belief, Defendants admit the allegations set forth in paragraph 1.
2. On information and belief, Defendants admit the allegations set forth in paragraph 2.
3. On information and belief, Defendants admit the allegations set forth in paragraph 3.
4. Defendants admit the allegations set forth in paragraph 4.
5. Defendants admit the allegations set forth in paragraph 5.
6. Defendants admit the allegations set forth in paragraph 6.

Jurisdiction and Venue

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants admit that Plaintiffs allege patent infringement and that Plaintiffs rely on the statutes cited in paragraph 7 as the basis for their cause of action and subject matter jurisdiction. Defendants admit that this Court has jurisdiction over the subject matter of this action.

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Mylan Inc. does not contest personal jurisdiction in this district for the purposes of this action only. Mylan Inc. admits that it operates an office at 405 Lexington Avenue, New York, NY 10174. Defendants deny the remaining allegations set forth in paragraph 8.

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Mylan Pharmaceuticals Inc. does not contest personal jurisdiction in this district for the purposes of this action only. Defendants deny the remaining allegations set forth in paragraph 9.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Matrix Laboratories Limited ("Matrix") does not contest personal jurisdiction in this district for the purposes of this action only. Defendants deny the remaining allegations set forth in paragraph 10.

11. Paragraph 11 contains conclusions of law and not averments of facts. Insofar as an answer is required, Defendants admit that venue appears to be proper under the statutory provisions cited by Plaintiffs. Defendants otherwise deny the remaining allegations set forth in paragraph 11.

Regulatory Requirement for Approval of New and Generic Drugs

12. Defendants admit the allegations in paragraph 12 to the extent they restate FDA regulatory requirements set forth in 21 U.S.C. §355(b). Defendants deny that the remaining allegations set forth in paragraph 12 accurately characterize the FDA drug approval process.

13. Defendants admit the allegations in paragraph 13 to the extent they restate FDA regulatory requirements set forth in 21 U.S.C. §355(j)(2)(A)(iv) and 21 U.S.C. §355(j)(8)(B). Defendants deny that the remaining allegations set forth in paragraph 13 accurately characterize the FDA drug approval process.

14. Defendants admit the allegations in paragraph 14 to the extent they restate FDA regulatory requirements set forth in 21 U.S.C. §355(j). Defendants deny that the remaining allegations set forth in paragraph 14 accurately characterize the FDA drug approval process.

15. Defendants admit the allegations in paragraph 15 to the extent they restate FDA regulatory requirements set forth in 21 U.S.C. §355(j)(2)(A)(i). Defendants deny that the remaining allegations set forth in paragraph 15 accurately characterize the FDA drug approval process.

16. Defendants admit the allegations in paragraph 16 to the extent they restate FDA regulatory requirements set forth in 21 U.S.C. §355(a). Defendants deny that the remaining allegations set forth in paragraph 16 accurately characterize the FDA drug approval process.

Plaintiffs' Approved Drug Product

17. On information and belief, Defendants admit the allegations set forth in paragraph 17.

18. On information and belief, Defendants admit the allegations set forth in paragraph 18.

19. On information and belief, Defendants admit the allegations set forth in paragraph 19.

20. Defendants admit that U.S. Patent No. 5,968,976 ("the '976 patent") is listed in the Orange Book in connection with NDA No. 21-468 and that Defendants have not previously challenged the listing of this patent in the Orange Book. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 20, and, therefore, deny them.

Mylan's ANDA

21. Defendants admit that on or before February 4, 2009, Matrix submitted its ANDA No. 90-976 and paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for lanthanum carbonate chewable tablets that are bioequivalent to Shire's Fosrenol® lanthanum carbonate chewable tablets. Defendants further admit that ANDA No. 90-976 seeks approval to engage in the commercial manufacture, use and sale of lanthanum carbonate chewable tablets (500, 750, and 1000 mg) before the expiration of U.S. Patent Nos. 7,465,465, 7,381,428, and 5,968,976. Defendants deny the remaining allegations set forth in paragraph 21.

22. Defendants admit that February 4, 2009, Mylan Inc. sent a letter dated February 4, 2009, advising Shire of Mylan Inc.'s paragraph IV certification relating to the '976 patent ("Mylan's Notice Letter")and that Mylan's Notice Letter included an offer of confidential access. Defendants refer to Mylan's Notice Letter for its contents. Defendants deny that Mylan's Notice Letter is attached to the Amended Complaint as Exhibit A, since Exhibit A to the Amended Complaint does not include the first seven pages of the February 4, 2009, letter. Defendants admit upon information and belief the allegations set forth in the last four sentences of paragraph 22.

23. Defendants admit the allegations set forth in paragraph 23.

24. Defendants admit that the sole indication set forth in the proposed labeling submitted by Mylan in its ANDA No. 90-976 for its proposed lanthanum carbonate chewable tablets is the reduction of serum phosphate in patients with end stage renal disease, the same indication as that set forth in the approved labeling for Shire's FOSRENOL® lanthanum carbonate chewable tablet products. Defendants deny the remaining allegations set forth in paragraph 24.

Count 1: Patent Infringement – '976 patent

25. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 24 as if fully set forth herein.

26. Defendants admit that the issue date set forth on the face of the '976 patent entitled "Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates" is October 19, 1999. Defendants aver on information and belief that the original expiration date of the '976 patent is March 19, 2016 and that a patent term extension certificate on the '976 patent sets forth on its face that the term of the patent was extended from the original expiration date for a period of 951 days, which is October 26, 2018. Defendants further admit that a copy of the '976 patent was attached to the Amended Complaint. Defendants deny the remaining allegations set forth in paragraph 26.

27. On information and belief, Defendants admit the allegation set forth in paragraph 27.

28. On information and belief, Defendants admit that Shire currently markets lanthanum carbonate chewable tablets in the United States under the trademark FOSRENOL®.

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 28.

29. Defendants deny the allegations set forth in paragraph 29.

30. Defendants deny the allegations set forth in paragraph 30.

31. Defendants admit that Matrix seeks FDA approval to engage in the commercial manufacture, use, and/or sale of a generic lanthanum carbonate product. Defendants deny the remaining allegations set forth in paragraph 31.

32. Defendants deny the allegations set forth in paragraph 32.

33. Defendants deny the allegations set forth in paragraph 33.

34. Defendants deny the allegations set forth in paragraph 34.

35. Defendants deny the allegations set forth in paragraph 35.

36. Defendants deny the allegations set forth in paragraph 36.

37. Defendants further answer that any allegations in the Amended Complaint requiring a response from Defendants not specifically admitted are denied.

38. Defendants also deny that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs A through G.

39. Defendants assert that this case is exceptional under 35 U.S.C. § 285.

Affirmative Defenses

40. Further responding to the Amended Complaint, and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Amended Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiffs.

First Affirmative Defense
(Non-infringement of the '976 patent)

41. The manufacture, use, offer for sale, sale, or importation of the lanthanum carbonate products that are the subject of ANDA 90-976 will not infringe any valid claim of the '976 patent.

Second Affirmative Defense
(Invalidity of the '976 patent)

42. All asserted claims of the '976 patent, if construed to encompass the lanthanum carbonate products that are the subject of ANDA 90-976, are invalid under 35 U.S.C. §§ 102, 103 or 112.

43. By way of additional example and not of limitation, one or more claims of the '976 patent are invalid for the reasons set forth in Mylan Inc.'s February 4, 2009 Letter, attached in part as Exhibit A to the Amended Complaint.

Third Affirmative Defense
(Failure to State a Claim)

44. The Amended Complaint fails to state a claim against Mylan Pharmaceuticals Inc. upon which relief can be granted.

Counterclaims

45. Further responding to the Amended Complaint, Defendants allege the following counterclaims against Shire Canada Inc., Shire International Licensing B.V., and Shire US Inc.

(collectively "Plaintiffs" or "Shire"), without admitting any allegation of the Amended Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiffs.

The Parties

46. Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania and has a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

47. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

48. Matrix Laboratories Limited ("Matrix") is a corporation organized and existing under the laws of India and has a principal place of business at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad - 500 003, Andhra, Pradesh, India.

49. On information and belief, Shire Canada Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 2250, boul. Alfred-Nobel, bureau 500, Ville St-Laurent, QC H4S 2C9, Canada.

50. On information and belief, Shire International Licensing B.V. is a corporation organized and existing under the laws of the Netherlands and has a principal place of business at Strawinskylaan 847, 1077 XX Amsterdam, Noord-Holland, The Netherlands.

51. On information and belief, Shire US Inc. is a corporation organized and existing under the laws of New Jersey and has a principal place of business at 725 Chesterbrook Blvd., Wayne, PA 19087, United States.

52. On information and belief, based upon the Amended Complaint, Shire is the holder of an approved new drug application ("NDA") 21-468 for lanthanum carbonate chewable tablets, marketed under the trademark Fosrenol®.

53. On information and belief, based upon the Amended Complaint, Shire owns and asserts the right to enforce U.S. Patent No. 5,986,976 ("the '976 patent").

Jurisdiction and Venue

54. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq*.

55. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the patents are not infringed and are invalid.

56. Venue is proper pursuant to 38 U.S.C. §§ 1391(b) and (c).

The Controversy

57. Matrix holds Abbreviated New Drug Application ("ANDA") No. 90-976 for lanthanum carbonate chewable tablets (500, 750, and 1000 mg).

58. On or about March 19, 2009, Plaintiffs filed the present action against Defendants alleging infringement of the '976 patent arising from Defendants' submission of ANDA No. 90-976.

59. On or about March 16, 2009, Plaintiffs filed an action against Barr Laboratories, Inc. (part of Teva Pharmaceutical Industries Ltd.) alleging infringement of the '976 patent as well as United States Patent Nos. 7.465,465 ("the '465 patent) and 7,381,428 ("the '428 patent").

60. On or about April 2, 2009, Plaintiffs filed an action against Natco Pharma Ltd. alleging infringement of the '976 and '428 patents.

Counterclaim Count 1
Declaratory Judgment of Non-infringement of the '976 Patent

61. Defendants repeat and incorporate by reference paragraphs 44-60.

62. The manufacture, use, offer for sale, sale or importation of the lanthanum carbonate products that are the subject of ANDA 90-976 will not infringe any valid claim of the '976 patent.

63. The filing ANDA 90-976 did not infringe the '976 patent because the manufacture, use, offer for sale, sale, or importation of the lanthanum carbonate products that are the subject of ANDA 90-976 will not infringe any valid claim of the '976 patent.

64. Because Defendants have not infringed and will not infringe any valid claim of the '976 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

Prayer for Relief

WHEREFORE, Defendants seek judgment against Plaintiffs as follows:

A. That Plaintiffs' Amended Complaint, and all of its causes of action, be dismissed with prejudice;

B. That judgment be entered in favor of Defendants, including an Order adjudging U.S. Patent No. 5,968,976 not infringed by Defendants;

C. That Defendants be awarded their fees and costs in defending this litigation pursuant to 35 U.S.C. § 285; and

D. That Defendants be awarded such other and further relief as the Court deems just and proper.

Dated: New York, New York
April 15, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of DEFENDANTS' ANSWER TO THE AMENDED COMPLAINT to be transmitted via ECF and e-mail on the 15th day of April, 2009 to Plaintiffs' counsel of record as listed below:

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Dated: April 15, 2009

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